January 13, 2010
Shionogi & Co., Ltd.

# Shionogi Receives Marketing and Manufacturing Approval of a Novel Anti-viral Drug for Influenza, "RAPIACTA 300mg Bag for Intravenous Drip Infusion" and "RAPIACTA 150mg Vial for Intravenous Drip Infusion"

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Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President: Isao Teshirogi; hereafter "Shionogi") today announced that it received marketing and manufacturing approval of a novel anti-viral drug for influenza, "RAPIACTA 300mg Bag for Intravenous Drip Infusion" and "RAPIACTA 150mg Vial for Intravenous Drip Infusion" (generic name: peramivir), on January 13, 2010. It is scheduled to be launched pending its National Health Insurance (NHI) price listing.

RAPIACTA, licensed from US-based BioCryst Pharmaceuticals, Inc. has been developed by Shionogi in Japan*. Shionogi received approval for both single dose administration for adult uncomplicated seasonal influenza infection as well as single or multiple dose administration for adult patients at high-risk. Shionogi has also completed a clinical study in pediatric patients with uncomplicated seasonal influenza and the Company will make its best efforts to file an additional application for the pediatric use of RAPIACTA within this fiscal year.
* The phase III multi-national Asian study for RAPIACTA was conducted in Japan, Taiwan and Korea.

Although the U.S. Food & Drug Administration (FDA) issued an Emergency Use Authorization (EUA) in the USA for intravenous administration of peramivir last October for the treatment of hospitalized adult and pediatric patients for whom therapy with an i.v. drug is clinically appropriate, the marketing and manufacturing approval of RAPIACTA received by Shionogi in Japan is the world's first formal marketing authorization of this drug. Shionogi believes that RAPIACTA represents an important therapeutic advance for patients with influenza.

Recognizing that novel anti-influenza drugs are needed for the H1N1 influenza pandemic, peramivir was designated as a priority review product by the Ministry of Health, Labour and Welfare in Japan. Shionogi has been making its maximum efforts to cooperate with the regulatory authorities in order to expedite the marketing and manufacturing approval of RAPIACTA. As a result, the Company achieved its objective of receiving a very rapid approval. During a fixed period following its launch, Shionogi will make efforts to collect data on all patients who receive RAPIACTA after launch in order to delineate its clinical utilization and safety further to keep health care professionals informed promptly of the proper use of the product.

Shionogi, as a leading company of anti-infective drugs, is committed to directing its resources into research and development and also into educational activities to contribute to the treatment of infectious diseases, especially of bacterial and viral origin.

**RAPIACTA for Intravenous Drip Infusion Product Overview**

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| Product Name: | RAPIACTA 300mg bag for intravenous drip infusion<br>RAPIACTA 150mg vial for intravenous drip infusion |
| Generic Name: | Peramivir |
| Indication: | Infection with influenza A or B virus strain |
| Form and Content: | 300mg of peramivir in one bag (60mL) for intravenous drip infusion<br>150mg of peramivir in one vial (15mL) for intravenous drip infusion |
| Dosage and Administration: | In general, a single dose of 300mg of peramivir is to be administrated to adult patients as intravenous drip infusion over longer than 15 minutes. For patients at high-risk, a single dose of 600mg of peramivir is to be administrated as intravenous drip infusion over longer than 15 minutes one time daily, but multiple daily doses are also a treatment option depending on the condition of the patient. The dosage should be adjusted according to the age or medical condition of the patient. |
| Approval Date: | January 13, 2010 |

**Forward-Looking Statements**

*This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.*

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